JUL 17 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

As required by section 807.92(c)

K080731

5 -1 GENERAL INFORMATION

Trade Name	PHARAON 980 ENDO application & EXO application
Classification Name	LASER INSTRUMENT, SURGICAL, POWERED
Class	II
Product Code	GEX
CFR section	878.4810
Device panel	General & Plastic Surgery
Legally marketed predicate devices	CERALAS D 980 LASER SYSTEM manufactured by BIOLITEC numerous 510Ks including K993911 and K024088
Submitter	OSYRIS 121 Rue Chanzy, BP 90140 59260 HELLEMMES FRANCE
Contacts	Pr JAOUAD ZEMMOURI CEO jaouad.zemmouri@osyris.com Phone ; +33 (0)3 20 67 59 97 Fax: +33 (0)3 20 04 46 24 Regulatory contact : Dr Isabelle DRUBAIX (Idée Consulting) idrubaix@nordnet.fr

5 -2. DEVICE DESCRIPTION

The medical device PHARAON 980 is based on the use of a laser module allowing the emission of a beam of coherent light at 970nm ± 10 nm at a maximum power of 25W. PHARAON 980 includes the whole of the supplies necessary to supply the laser and to ensure its thermalisation using a Peltier element built on a ventilated radiator.

PHARAON 980 includes the whole of electronics and the functions allowing the parameter setting of the laser and the safe functioning of the device. The adjustments of the parameters are done using a TFT screen and a tactile flagstone.

PHARAON 980 is available for ENDO application (endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux) and EXO application (photocoagulation of teleangectasia of the legs).

PHARAON 980 EXO is supplied with CONTROL4+ HANDPIECE a dedicated handpiece including an auto-regulated cooling system and video allowing optimal mapping of the treatment area and screen display of the vessel on PHARAON 980.

5 - 3. INTENDED USE

PHARAON 980 ENDO is indicated for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

PHARAON 980 EXO is indicated for photocoagulation of teleangectasia of the legs.

5 - 4. PERFORMANCE DATA

PHARAON 980 ENDO & EXO applications conform to Guidance on the content and organization of a premarket notification for a medical laser (June 1995) and to Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005).
PHARAON 980 ENDO & EXO applications conform to 21 CFR part 1040.10 and 1040.11.
Performance data demonstrate the safety and effectiveness of PHARAON ENDO /EXO for its intended use.

5 - 5. SUBSTANTIAL EQUIVALENCE

PHARAON 980 ENDO & EXO applications have the same intended use, design and function as predicate devices CERALAS D980 LASER SYSTEM manufactured by BIOLITEC.

Summary preparation date: March, 7, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2008

Osyris
% Pr Jaouad Zemmouri
CEO
121 Rue Chanzy B.P. 90140
Hellemmes, France

Re: K080731
Trade/Device Name: PHARAON 980 ENDO & EXO
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical insgrument for use in general and plastic surgery and ~~in dermatology~~
Regulatory Class: II
Product Code: GEX
Dated: June 12, 2008
Received: June 17, 2008

Dear Pr Jaouad Zemmouri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K080731

Device Name: **PHARAON 980 ENDO & EXO**

Indications for Use:

PHARAON 980 ENDO is indicated for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

PHARAON 980 EXO is indicated for photocoagulation of teleangectasia of the legs.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080731